FDA 510(k) Premarket Notification

K220729 The Luminance RED Acne Device

CLEARED

Jun 9, 2022
87 days to decision

K220729 · Product code: **OLP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220729/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Mar 14, 2022
Decision date	Jun 9, 2022
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Luminance Medical Ventures, Inc.**
Location	Dallas, TX, US
Contact	Troy Stites
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**leanRAQA, LLC**
Contact	Laura Nygard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov